Remarks

I. Support for the Amendments

Support for the foregoing amendments to the claims may be found throughout the specification, for example at page 25, lines 5-11, page 6, lines 1-6, and at page 14, line 16, and in the original claims. No new matter was added by way of these amendments.

II. Status of the Claims

By the foregoing amendments, claims 1-78 and 82-90 have been canceled, and claims 79, 81, 91, 97, 109, 115 and 121 have been amended. Upon entry of the foregoing amendments claims 79-81 and 91-126 are pending in the present application, with claims 79, 91, 97, 103, 109, 115 and 121 being the independent claims.

III. Summary of the Office Action

In the Office Action dated December 19, 2000, the Examiner has made one objection to the priority claim, one objection to the oath/declaration, one objection to the information disclosure statement, one objection to the specification, one provisional rejection of the claims, and three rejections of the claims. Applicants respectfully offer the following remarks to overcome or traverse each of the elements of the Office Action.

IV. The Objection to the Priority Claim

In the Office Action at page 2, section 4, the Examiner objects to the priority claim because it is not located in the first sentence of the application. By the foregoing amendments the paragraph beginning at line 9 of the specification, containing the claim to priority, has been moved to the first sentence of the application. As such, Applicants assert that the priority claim is perfected under 37 C.F.R. § 1.78.

V. The Objection to the Oath/Declaration

In the Office Action at page 3, section 5, the Examiner has objected to the oath/declaration as being defective. Applicants have submitted a new oath/declaration with this reply; as such, Applicants assert that the oath/declaration is now in compliance with 37 C.F.R. § 1.67(a).

VI. The Objection to the Information Disclosure Statement

In the Office Action at page 4, section 4, the Examiner has objected to the information disclosure statement for an incorrectly cited date in reference AL10. Applicants have submitted a supplemental information disclosure statement with this response, correcting the citation of reference AL10. As such, Applicants assert that the information disclosure statement is now in compliance with 37 C.F.R. § 1.98(a)(2).

Additionally, in the Office Action at page 4, section 4a, the Examiner has objected to the information disclosure statement for citing pending U.S. Applications that do not have publication dates. We thank the Examiner for his willingness to consider the applications when

they become available. Applicants request that the Examiner inform us when these applications are available, and request that the Examiner make them of record at that time.

VII. The Objection to the Specification is Traversed

In the Office Action at page 4, section 7, the Examiner has objected to the use of URLs in the specification. Applicants respectfully traverse this objection.

In support of this objection the Examiner claims:

> Embedded hyperlinks and/or other forms of browser-executable code are impermissible and must be deleted . . . . Furthermore if the application should issue and be placed on the Office web page, the URL may be interpreted as a valid HTML code and become a live web link, transferring the user to a commercial web site (in the instant case, Aerie Corporation, Birmingham, MI).

Office Action, page 5, section 7. Applicants respectfully disagree.

A URL is not considered to be browser executable code if it is not either preceded with *http://* or placed between the symbols "< >." M.P.E.P. § 608.01, page 600-54, Examiner Note. As such, the URL included in the specification at page 53, lines 7-9, is not browser executable code, and would therefore not be interpreted by a browser as a link to another web site when the document is placed on the USPTO web site. Reconsideration and withdrawal of this objection are respectfully requested.

VIII. The Obviousness-Type Double-Patenting Rejection

In the Office Action at pages 5 and 6, sections 8 and 9, the Examiner has rejected claims 79, 91, 92, 94, 97, 98 and 100 under the judicially created doctrine of obviousness-type double-

patenting as being unpatentable over claims 34-37 of commonly owned U.S. Patent Application No. 08/938,669 (the '669 application) now U.S. Patent No. 6,171,788. Applicants respectfully traverse this rejection. However, Applicants respectfully request that the Examiner hold this rejection in abeyance until identification of patentable subject matter in the present application, at which time Applicants will consider filing a terminal disclaimer.

IX. The Rejection of claims 79-81 and 91-126 Under 35 U.S.C. § 101

In the Office Action at page 6, sections 10 and 11, the Examiner has rejected claims 79-81 and 91-126 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claims 79-81, 91, 97, 103, 109, 115 and 121 have been amended to recite the phrase "substantially purified," thereby rendering this rejection moot. Reconsideration and withdrawal of this rejection are respectfully requested.

X. The Rejection of Claims 79-81, 97-102, 109-114 and 121-126 Under 35 U.S.C. § 112, First Paragraph is Traversed

In the Office Action, at page 7, section 13, the Examiner has rejected claims 79-81, 97-102, 109-114 and 121-126 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an enabling disclosure. Applicants respectfully traverse this rejection.

In support of this rejection the Examiner asserts:

> The specification does not provide particular guidance or direction for a fragment with function of any length. The term fragment would encompass a single nucleotide. The specification does not teach how to make and use fragments of SEQ ID 1-3 or 34 comprising a nucleotide less than six nucleotides in length that would have biological function.

Office Action, page 7, section 13. Applicants respectfully disagree. First, the specification provides guidance on the length of fragments of the invention. The specification defines the length of a fragment at page 25, lines 5-11, and defines the length of oligos *inter alia* at page 28. Second, the specification provides extensive guidance on the biological function of these fragments. *see, e.g.,* pages 25-25. Nevertheless, in order to promote speedy prosecution of the application, by the foregoing amendments claims 79, 109 and 121 have been amended to include the language "at least about 8 nucleotides in length." As such, the Examiner's rejection has been rendered moot. Reconsideration and withdrawal of the rejection of claims 79-81, 97-102, 109-114 and 121-126 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

XI. The Rejection of Claims 97-102, 109-114 and 121-126 under 35 U.S.C. § 102(b) is Traversed

In the Office Action at page 8, section 15, the Examiner has rejected claims 97-102, 109-114, and 121-126 under 35 U.S.C. § 102(b) as being anticipated by Escribano *et al.*, J. Biochem 118: 921 (1995). Applicants respectfully traverse this rejection.

In support of this rejection the Examiner contends:

> Escribano et al., J. Biochem. 118(5), 921-931 (1995), throughout the article and especially at p. 921, para 3-4, and p. 929, para 4, teach a fragment of SEQ ID 1-3 and 34 that is nucleotides 4862-5300 of SEQ ID 1-3 and 4, (as evidenced by Escribano et al., Gen Bank, Accession NO.AB006686), phage vectors thereof and XL1;Blue cells thereof, and which further comprises a glucocorticoid response motif, a shear stress response motif and a NFκB motif...

Office Action, page 8, section 15(a). Applicants respectfully disagree with this contention.

Escribano *et al.* does not disclose any sequence information.

The rejected claims relate to nucleic acid molecules comprising a nucleotide sequence selected from the group consisting of fragments of SEQ ID NO: 1-3 and 34, wherein the nucleotide sequence comprises a functional regulatory region, and is at least about 8 nucleotides in length, and to cells and vectors comprising these nucleic acid molecules.

Under 35 U.S.C. § 102(b), a claim can only be anticipated if every element in the claim is disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). Because Escribano *et al.* do not disclose the nucleotide sequence of SEQ ID NO: 1-3 or 34, it cannot anticipate the amended claims. The Examiner appears to rely on the mention of Escribano *et al.* in the GenBank report as evidence of what Escribano *et al.* disclose. This reliance is improper.1 Moreover, the GenBank report for AB006686 was submitted to GenBank on August 16, 1997, which is after Applicants' earliest priority date. Therefore, the GenBank report, is not prior art under 35 U.S.C. § 102. Reconsideration and withdrawal of the rejection of claims 97-102, 109-114, and 121-126 under 35 U.S.C. § 102(b) is respectfully requested.

XVI. Summary

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn.

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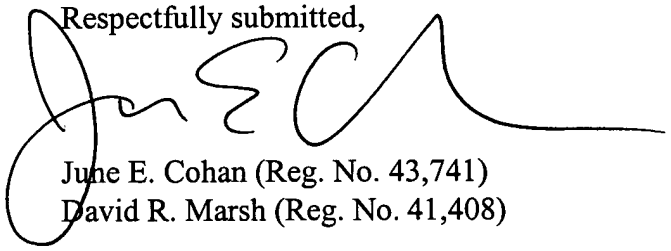
1 It is well-established law that a nucleic acid is not defined or described by its name (*e.g.*, a cDNA encoding insulin), but "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA." *Regents of the University of California v. Eli Lilly* and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,



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Version with markings to show changes made

In the Specification (Page 1):

~~**FIELD OF THE INVENTION**~~

~~The present invention relates to the field of diagnostic and prognostic methods and kits, treatments, and compositions useful in understanding and identifying glaucoma, related intraocular pressure disorders, and steroid sensitivity.~~

~~**CROSS REFERENCE TO RELATED APPLICATIONS**~~

~~This application is a continuation in part of U.S. Patent Application serial no. 08/938,669, filed September 26, 1997, specifically incorporated by reference herein, which is a continuation in part of U.S. Patent Application serial no. 08/791,154, filed January 28, 1997, also specifically incorporated by reference herein.~~

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Patent Application serial no. 08/938,669, filed September 26, 1997, now issued as U.S. Patent No. 6,171,788, specifically incorporated by reference herein, which is a continuation-in-part of U.S. Patent Application serial no. 08/791,154, filed January 28, 1997, now abandoned, also specifically incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates to the field of diagnostic and prognostic methods and kits, treatments, and compositions useful in understanding and identifying glaucoma, related intraocular pressure-disorders, and steroid sensitivity.

In the claims:

79. A substantially purified nucleic acid comprising a nucleotide sequence selected from the group consisting of one of SEQ ID NO: 1-3 or 34, and a fragment of SEQ ID NO: 1-3, or 34 that possesses a functional regulatory region and is at least about 8 nucleotides in length.

81. A vector comprising a substantially purified nucleic acid as claimed in claim 79.

91. An substantially purified nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID NO: 1-3 and 34, wherein the nucleotide sequence comprises a functional regulatory region.

97. An substantially purified nucleic acid comprising a nucleotide sequence selected from the group consisting of fragments of SEQ ID NO: 1-3 and 34, wherein the nucleotide sequence comprises a functional regulatory region.

109. A cell comprising an introduced nucleic acid, wherein the nucleic acid comprises a nucleotide sequence selected from the group consisting of fragments of SEQ ID NO: 1-3 and 34, wherein the nucleotide sequence comprises a functional regulatory region and is at least about 8 nucleotides in length.

115. A vector comprising a substantially purified nucleic acid, wherein the nucleic acid comprises a nucleotide sequence selected from the group consisting of SEQ ID NO: 1-3 and 34, wherein the nucleotide sequence comprises a functional regulatory region.

121. A vector comprising a substantially purified nucleic acid, wherein the nucleic acid comprises a nucleotide sequence selected from the group consisting of fragments of SEQ ID NO: 1-3 and 34, wherein the nucleotide sequence comprises a functional regulatory region and is at least about 8 nucleotides in length.